



# EU Quality Management Certificate



This is to certify that the company

## I TP Innovative Tomography Products GmbH

Universitätsstraße 136  
44799 Bochum  
Germany

SRN: DE-MF-000008634

has established, implemented and maintains a Quality Management System in accordance with

### **Annex IX, Chapter I and III of the Regulation (EU) 2017/745** Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3. Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	535006 MDR2017Q
Certificate ID	1000303552
Effective date	2026-03-10
Expiry date	2030-02-18
Frankfurt am Main,	2026-03-10



## DQS Medizinprodukte GmbH

Heinrich von Mettenheim  
Managing Director



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main  
**DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.**  
The validity of the certification can only be verified by the QR-code.



**Annex to EU Quality Management Certificate**  
**SRN of Manufacturer: DE-MF-000008634**  
**Certificate ID: 1000303552**

**Device categories and variants covered by this certificate according to Article 52:**

Device category: **MDN 1208 - Non-active non-implantable instruments**  
Product name: Interventional Needle KIR/ KIM  
Risk classification: IIa  
Basic-UDI-DI: 426241068KIRKIM94  
Intended purpose: This needle is intended for puncture and injection. This needle is NOT intended for use on the central circulatory system or the central nervous system.

Device category: **MDN 1208 - Non-active non-implantable instruments**  
Product name: Semi-automatic biopsy needle BIM, BIM(i)  
Automatic biopsy needle BAM  
Risk classification: IIa  
Basic-UDI-DI: 426241068BIMBAM27  
Intended purpose: The biopsy needle is intended for biopsies of soft tissue (e.g., breast, kidney, liver, prostate).

**Examinations and tests performed:**

535006\_A212101MED\_01 dated 2023-07-02  
535006\_A212101MED\_02 Interventional Needle KIR/ KIM dated 2024-10-25  
535006\_A217586MED\_03 Semi-automatic biopsy needle dated 19.02.2026

**Further conditions for or limitations to the validity of the certificate:**

n/a

**Reference to previous certificates:**

Revision	Date of Issue	Certificate-ID	Description of change
01	2025-02-19	1000214766	Product listing "Semi-automatic biopsy needle"